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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/533,054	04/27/2006	Pieter Johan Peeters	PRD-2009-USPCT1	9048

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EXAMINER

KAPUSHOC, STEPHEN THOMAS

ART UNIT	PAPER NUMBER
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1634

MAIL DATE	DELIVERY MODE
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04/01/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/533,054	Applicant(s) PEETERS ET AL.	
	Examiner Stephen Kapushoc	Art Unit 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 and 16-32 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-14 and 16-32 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input checked="" type="checkbox"/> Other: <u>renumbered claims</u> . |

DETAILED ACTION

37 CFR 1.126 - Renumbering of claims

It is noted that the claims as presented contain two claims indicated by the same claim number, i.e. there are two claims indicated as claim 14. In order to make the claim numbering compliant with the rules, claims 14-31 of the amended claims of 04/27/2005 have been renumbered as claims 15-32; furthermore the claim numbers of claims referenced within the claims have been corrected to conform to the renumbered claims. It is suggested that Applicants thoroughly review all claim numbers to ensure the claims are presented as intended, particularly renumbered claims 16-21 and 27. The numbering of the claims as renumbered is used for purposes of this Lack of unity restriction requirement, and must be used by Applicants in any future correspondence pertaining to the instant application.

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claim(s) 1-5, drawn to methods of diagnosing a CRH induced gene expression profile comprising transcription analysis.

Group 2, claim(s) 6-13, 16-21 and 32, drawn to drawn to methods of diagnosing a CRH induced gene expression profile comprising determining protein amounts.

Group 3, claim(s) 14 and 22-25, drawn to methods of identification of compounds that alter CRH signaling response comprising analysis of protein amounts.

Group 4, claim(s) 26-31, drawn to nucleic acids and vectors and host cells comprising said nucleic acids.

Art Unit: 1634

Further Lack of unity Restriction Requirement:

If Applicants elect the invention of Group 1, Applicants shall further select a single particular gene as identified by SEQ ID NO: from those SEQ ID NOs recited in claim 1. It is noted that, relevant to Group 1, claim 3 requires a combination of all of the SEQ ID NOs recited in claim 3, whereas claims 1 and 4 require only a single particular gene. If Applicants elect the invention of Group 1, claim 3 will be examined as it requires the full combination of recited sequences, and claims requiring only a subcombination of sequences will be examined in so far as they require the selected single particular gene.

If Applicants elect the invention of Group 2, Applicants shall further select a single specific combination of proteins as identified by SEQ ID NO: from those SEQ ID NOs recited in claim 6. It is noted that claim 6 encompasses any combination of 'at least one protein that modulate corticotropin releasing hormone (CRH)'. The claims will be examined in so far as they require the selected specific combination of protein, and any claims specifically requiring the analysis of only non-elected protein will be withdrawn from examination as to a non-elected invention. Applicants shall further indicate which polynucleotides (e.g. as recited in claim 21) encode any selected polypeptides.

If Applicants elect the invention of Group 3, Applicants shall further select a single specific combination of proteins as identified by SEQ ID NO: from those SEQ ID NOs recited in claim 14. It is noted that claim 14 encompasses any combination of 'at least one protein that modulate corticotropin releasing hormone (CRH)'. The claims will be examined in so far as they require the selected specific combination of genes, and any claims specifically requiring the analysis of only non-elected proteins will be withdrawn from examination as to a non-elected invention.

If Applicants elect the invention of Group 4, Applicants shall further select a single particular nucleic acid sequence from the group consisting of SEQ ID NO: 1-8 and 25-31, as recited in claims 25 and 27. The claims will be examined in so far as they require the selected specific nucleic acid sequence, and any claims requiring only a non-elected sequence will be withdrawn from examination as to a non-elected invention.

2. The inventions listed as Groups 1-4 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

3. The common technical feature of the claims of Groups 1-4 is the various nucleic acids and polypeptides of SEQ ID NO: 1-41 as recited in the claims. However, such a common technical feature is not a special technical in view of the teachings of the prior art as the polypeptides and the nucleic acids that encode the polypeptides were known

Art Unit: 1634

in the prior art. For example, where positions 218-1312 of SEQ ID NO: 11 encode SEQ ID NO: 12, the polypeptide sequence of SEQ ID NO: 12 is known in the prior art and is taught by GenBank Locus AAC34301.1 (12-Dec-2000). And the sequence of SEQ ID NO: 1 is taught by EMBL AI842377 (04-Mar-2000). As such the common technical feature is not a special technical feature.

Furthermore, with regard to the further lack of unity requirement, it is noted that the different genes and proteins are distinct from one another as they are composed of different nucleotide and amino acid sequences that are structurally different from one another, and the different genes and proteins do not in fact share any structural elements (i.e. nucleotide or amino acid sequences) related to any functionality required by the claims.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

5. The examiner has required restriction between product and process claims.

Where applicant elects claims directed to the product, and the product claims are

Art Unit: 1634

subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder.

All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen Kapushoc whose telephone number is 571-272-3312. The examiner can normally be reached on Monday through Friday, from 8am until 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached at 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

Art Unit: 1634

you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days.

Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

/Stephen Kapushoc/
Art Unit 1634